REMARKS

I. Preliminary Amendment

Applicants filed a Preliminary Amendment on June 24, 2002 in the referenced application by facsimile. Applicants' file contain an Auto-Reply Facsimile Transmission confirming receipt of the Preliminary Amendment by the PTO. However, the Preliminary Amendment apparently was not entered in the application file, and a first Office Action was issued on August 14, 2002 based on the application as originally filed, and not as amended by the Preliminary Amendment.

Applicants' Agent contacted the Examiner on August 20, 2002 to obtain clarification and instructions on how to proceed. The Examiner instructed Applicants to resubmit the claim amendments presented in the unentered Preliminary Amendment in their response to the outstanding Office Action. Accordingly, Applicants are including their previous amendments in this communication, and will not re-submit a copy of the Preliminary Amendment. The Examiner is requested to contact Applicants' Agent if a copy of the unentered Preliminary Amendment is desired. For the record, the claim amendments in this Amendment are identical to the claim amendments presented in the Preliminary Amendment.

II. Amendments

Claims 1-20 and 24-41 have been amended to more clearly define the invention and to place the claims in accordance with U.S. patent practice. The exemplary embodiments recited in claims 10-12, 20, 33, 34, and 41 have been deleted and embodied in new claims 43-46, 48, and 50-53. The dependencies of claims 3-7, 9-20, 26, 28-31, and 33-41 have been amended to remove the occurrence of an improper multiple claim dependency. In this regard, claims 10 and

12-14 have been amended to incorporate the embodiment of claim 7, and claims 33-36 have been amended to incorporate the embodiment of claim 32. Claim 27 has been amended to substitute the term "chamber" for the term --housing--. Support for the amendment is found on page 7, lines 15-24, of the specification.

Claims 22 and 23 have been amended to recite a method for controlling the coating process of a batch of particles which are monitored in accordance with the claimed invention. Support for the amendments to claims 22 and 23 is found on page 5, lines 5-35. Claim 21 has been canceled.

New claim 42 is directed to an embodiment of the invention deleted from claim 10 and comprises a combination of claims 7 and 10. New claim 47 is directed to an embodiment of the invention deleted from amended claim 13. New claim 49 is directed to an embodiment of the invention deleted from claim 33 and comprises a combination of claims 33 and 32.

Upon entry of this Amendment, claims 1-20 and 22-53 are pending. No new matter has been added by any amendments herein.

III. Claim objections and rejections

Claims 4-21, 23, and 28-41 are objected to under 37 C.F.R. § 1.75(c) as allegedly being in improper form because a multiple dependent claim cannot depend from another multiple dependent claim. These claims have been amended to remove instances of improper multiple dependency, and therefore withdrawal of the objection to claims 4-21, 23, and 28-41 is requested.

Claim 22 is rejected under 35 U.S.C. § 101 as allegedly being directed to the use of a method for coating a substrate particle. Claim 22 has been amended to recite a method for controlling the coating process of a batch of particles, rather than the use of the method. Accordingly, withdrawal of the rejection of claim 22 under §101 is requested.

Claims 1-3 and 24-27 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to make and/or use the invention. The Examiner alleges that neither the specification nor the claims explain how to make the spectrometric measurement and use the measurement data to derive a measurement value related to the coating.

Enablement cannot be determined in a vacuum. Rather, the test for determining whether the specification meets the enablement requirement requires a consideration of the following undue experimentation factors as set forth in M.P.E.P. §2164.01(a):

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicants submit that the specification is enabling with respect to the claimed invention. In the first instance, the level of one of ordinary skill in the art **(Factor D)** is such that the skilled artisan is knowledgeable and experienced in performing spectrometric measurements to obtain a measurement value. At the time the priority application was filed, i.e., January 13, 2000, the

literature was replete with publications dealing with methods of spectrometry and an apparatus therefor (**Factors B and C**). Thus, at the time of filing, spectrometry was a well known and established field with a high level of skill in the art. In this regard, Applicants rely on the prior art of record, in particular US 5,518,759. Accordingly, as evidenced by the prior art disclosing spectrometric analyses in various applications, Applicants submit that the performance of spectrometric measurement, as contemplated by the claimed invention, has an acceptable level of predictability (**Factor E**).

Moreover, the specification provides a sufficient amount of direction, including a description of a preferred embodiment (**Factor F**), such that undue experimentation would not be required of the person of ordinary skill to practice the claimed invention (**Factor H**). In this regard, the Examiner's attention is directed to the specification at page 6, line 35 to page 7, line 2, where it teaches that:

> "[p]referably, the spectrometric measurement is performed by means of near infrared spectrometry and/or a spectrometric method based on Raman scattering and/or a spectrometric method based on absorption in the UV, visible, or infra-red (IR) wavelength region, or luminescence, such as fluorescence emission, and/or imaging spectrometry."

Each of the disclosed examples of spectrometric measurement are well known and within the expertise of the person of ordinary skill in the art. Furthermore, Applicants refer to page 9, lines 4-10, for additional disclosure on how to make the spectroscopic measurement. In this lines, it is stated that:

> "the spectrometric measurement can be carried out in such a manner that the particle P, the coating thickness of which is to be measured, is positioned at a desired level with respect to the measurement unit 4. Thus, the mean coating thickness or a variation of the coating thickness can be measured. Imaging spectrometry also allows for

> variations in the position of the particle P during the spectrometric measurement."

A patent need not teach, ***and preferably omits***, what is well known in the art. (M.P.E.P. §2164.01 and the case law cited thercin) (Emphasis added). Therefore, in view of the direction provided by the specification and based on the level of ordinary skill, no undue experimentation would be required to practice the claimed invention.

For a disclosure of using the measurement data to derive a measurement value related to the coating, Applicants direct the Examiner's attention to the specification at page 9, lines 12-19. This disclosure states that:

> "[I]n one embodiment, the evaluation [of the sample vector] is performed by subjecting the sample vector to a mathematical analysis, weighing the data, in conjunction to previous data, and condensing them to at least one measurement value. In the present embodiment chemometric methods are used. More particularly and at least in the case of continuous measurements during the coating process, a multivariate analysis, such as PCA (Principal Component Analysis), or PLS (Partial Least Squares) is performed on the sample vector.
>
> In this way, it is possible to directly measure the quality of the coating, in terms of relevant physical and/or chemical properties. As a further example, the heat transfer to the coating can be monitored by way of extracting a measurement value related to the surface temperature of the coating."

Therefore, the specification teaches how the measurement value related to the coating can be derived from the measurement value, for example, by using multivariate analysis such as principal component analysis or partial least squares analysis. Once again, these techniques are well know and within the expertise of the person of ordinary skill in the art.

In conclusion, Applicants submit that the undue experimentation factors (M.P.E.P. §2164.01(a)), as discussed above, weigh in favor of a favorable determination that the

specification meets the enablement requirement. Accordingly, withdrawal of the §112 rejection of claims 1-3 and 24-27 is requested.

The following documents have been made of record but not relied upon in support of a prior art rejection: US 5,518,759 to Sevillano et al; and US 5,871,805 to Lemelson. Applicants submit that the cited documents neither disclose nor suggest the claimed invention.

CONCLUSION

Applicants have made a good faith effort to respond to the outstanding Office Action. Applicants submit that the pending claims are in condition for allowance, which action is urgently requested.

Authorization is hereby given to charge any fee due in connection with this communication to Deposit Account No. 23-1703.

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Respectfully submitted,

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Claims 1-20 and 22-41- Version with markings to sh w changes made

1. A method for [of] monitoring the formation of a coating on a single particle [(P)], comprising the steps of:

(a) arranging the particle [(P)] at a given spatial location;

(b) forming the [said] coating on the particle [(P)]; and

(c) performing a spectroscopic measurement on the coating while the coating is being formed on the particle to obtain [obtaining] a measurement value of at least one principal parameter related to the [said] coating [, characterized in that said measurement value is obtained by performing a spectrometric measurement on said coating during said step of forming said coating].

2. [A] The method as set forth in claim 1, wherein the [said] spectrometric measurement is performed continuously during at least part of the coating formation step to generate [of forming the said coating, thereby generating] a sequence of measurement values of the [said at least one] principal parameter.

3. [A] The method as set forth in claim 1 [or 2], wherein the [said] step of arranging the particle [(P)] at the [a] given spatial location comprises [includes] fluidizing the [said] particle [(P)] on an upwardly directed gas flow.

4. [A] The method as set forth in claim 3 [any one of claims 1-3], wherein the coating formation [said step of forming said coating on the particle (P)] comprises [includes] generating a single droplet [(D)] of a coating fluid, and bringing the [said] droplet to impinge [on] upon the [said] particle [(P)].

5. [A] The method as set forth in claim 4 [claims 3 and 4], wherein the [said] droplet [(D)] upon [said] generation is moved into and allowed to follow the [said] upwardly directed gas flow to the [said] particle [(P)].

6. [A] The method as set forth in claim 4 [or 5], wherein the step of generating a [said] single droplet [(D)] is repeated [repeatedly generated], thereby forming at least one stream of [such] droplets [(D) that] which sequentially impinge upon the [on said] particle [(P)].

7. [A] The method as set forth in claim 1 [any one of the preceding claims], further comprising the [a] steps of:

monitoring at least one control parameter related to the particle or its environment [of the particle (P) or the particle (P) itself,]; and

[a step of] identifying a functional relationship between the [said at least one] control parameter and the [said at least one] principal parameter.

8. [A] The method as set forth in claim 7, further comprising the [a] step of generating [, based on said functional relationship for said single particle (P),] an aggregate model for prediction of the influence of the [said at least one] control parameter on the [said at least one] principal parameter for a large number of [such] particles [(P)] based on the functional relationship for the single particle.

9. [A] The method as set forth in claim 7 [or 8], further comprising the step of adjusting the [changing said at least one] control parameter [based,] at least partly [,] on the basis of the [said] measurement value.

10. [A] The method as set forth in [any one of claims 7-9 in combination with] claim 3 [or 5], further comprising the steps of:

a) monitoring at least one control parameter related to the particle or its environment; and

b) identifying a functional relationship between the control parameter and the principal parameter,

wherein the [said at least one] control parameter comprises [includes] a property of the [said] gas flow [, such as a flow rate, a temperature or a content of a solvent].

11. [A] The method as set forth in claim 7 [any one of claims 7-9], wherein the [said at least one] control parameter comprises [includes] a property of the particle [(P), such as a size, a shape, a density or a porosity].

12. [A] The method as set forth in claim 4 [any one of claims 7-9 in combination with any one of claims 4-6], further comprising the steps of:
monitoring at least one control parameter related to the particle or its environment; and
identifying a functional relationship between the control parameter and the principal parameter,

wherein the [said at least one] control parameter comprises [includes] a property of the [said] droplet [(D), such as a droplet size, a droplet generation rate or a concentration of a droplet constituent].

13. [A] The method as set forth in claim 4 [any one of claims 7-9 in combination with any one of claims 4-6], further comprising the steps of:
monitoring at least one control parameter related to the particle or its environment; and
identifying a functional relationship between the control parameter and the principal parameter,

wherein the [said at least one] control parameter comprises [includes a] the duration of a wetting period during the coating formation step [said step of forming said coating, said wetting period being effected by controlling said droplet generation].

14. [A] The method as set forth in claim 4 [any one of claims 7-9 in combination with any one of claims 4-6], further comprising the steps of:
monitoring at least one control parameter related to the particle or its environment; and
identifying a functional relationship between the control parameter and the principal parameter,

wherein the [said at least one] control parameter comprises the [includes a] duration of a drying period during the coating formation step [said step of forming said coating].

15. [A] The method as set forth in claim 1 [any one of the preceding claims], wherein the [said] step of obtaining the [said] measurement value comprises:

c1) [includes] generating a sample vector of measurement data from the [said] spectrometric measurement; [,] and

c2) condensing the [said] measurement data into the [said] measurement value of the [said at least one] principal parameter.

16. [A] The method as set forth in any one of claims 1-15 and 42-47 [the preceding claims], wherein [said] the spectrometric measurement is performed by means of near-infrared spectrometry.

17. [A] The method as set forth in any one of claims 1-15 and 42-47 [the preceding claims], wherein the [said] spectrometric measurement is performed by means of a spectrometric method based on Raman scattering.

18. [A] The method as set forth in any one of claims 1-15 and 42-47 [the preceding claims], wherein the [said] spectrometric measurement is performed by means of a spectrometric method based on absorption in the UV, visible, or infrared (IR) wavelength region, or luminescence or [, such as] fluorescence emission.

19. [A] The method as set forth in any one of claims 1-15 and 42-47 [the preceding claims], wherein the [said] spectrometric measurement is performed by means of imaging spectrometry.

20. [A] The method as set forth in any one of claims 1-15 and 42-47 [the preceding claims], wherein the [said] particle [(P)] is a pharmaceutical product [, such as a pellet a tablet or a capsule].

22. (Amended) [Use of a method as set forth in claim 2] A method for controlling the [of a] coating process of a batch of particles, comprising the steps of:

a) monitoring the coating formation according to claim 2;

b) using the [wherein said] sequence of measurement values of the principal parameter [is used] as a sequence of reference values in the [said] control; [,] and [wherein]

c) obtaining a corresponding spectroscopic measurement [is effected] on the [said] batch of particles to provide a sequence of actual values for the [said] control.

23. (Amended) [Use of a method as set forth in any one of claims 1-20] A method for controlling the [of a] coating process of a batch of particles, comprising the steps of: [, wherein]

a) monitoring the coating formation according any one of claims 1-15 and 42-47;

b) identifying a functional relationship [is identified] between [said] at least one principal parameter and at least one simultaneously-monitored control parameter, wherein the control parameter [which] is related to an environment of a [said] single particle of the batch; [(P); wherein].

c) selecting one or more [of said at least one] control parameters, based on the [said] functional relationship, [is selected] to represent one or more of the [said at least one] principal parameters;

d) determining [wherein] a desired sequence of values of the [said one or more] selected control parameter(s) [parameters is determined] for the [said] single particle [(P)]; and [wherein said]

e) controlling the coating process of the [a] batch of particles [is controlled] based on the [said] desired sequence of selected control parameter values.

24. An apparatus for monitoring the formation of a coating on a single particle [(P),] comprising:

means [(2, 5, 6, 9)] for arranging the [said] particle [(P)] at a given spatial location; [, and]

a fluid supply unit for applying [(3) adapted to apply] a coating fluid to the [said] particle to form a coating; and [(P) such that said coating is formed, characterized by]

a measurement unit [(4)] which [is adapted to] performs a spectrometric measurement on the [said] coating during formation thereof, and [to] derives a measurement value of at least one principal parameter related to the [said] coating.

25. [An] The apparatus as set forth in claim 24, wherein the [said] measurement unit [(4) is adapted to] continuously performs the [said] spectrometric measurement [,] and thereby generates [generating] a sequence of measurement values of the [said at least one] principal parameter.

26. [An] The apparatus as set forth in claim 24 [or 25], wherein the [said] particle arranging means [(2, 5, 6, 9)] comprises a flow unit [(2)] which [is adapted to] generates a fluidizing gas flow upon [on] which the particle [(P)] is fluidized.

27. [An] The apparatus as set forth in claim 26, further comprising a chamber [housing (1)] in which the [said] coating is formed on the [said] particle [(P)], wherein the [said] flow unit [(2) is adapted to] provides a shielding gas inside the chamber [housing (1)] intermediate the measurement unit [(4)] and the location of the [said] particle, and wherein the [(P), said] shielding gas is substantially [being essentially] identical to the gas used for fluidizing the [said] particle [(P)].

28. [An] The apparatus as set forth in claim 24 [any one of claims 24-27], wherein the [said] fluid supply unit [(3) is operable to] generates a single droplet of the coating fluid which [(D) that] is brought to impinge upon the [on said] particle [(P)].

29. [An] The apparatus as set forth in claim [26 and] 28, wherein the [said] fluid supply unit [(3) is arranged to] injects each droplet of the coating fluid [(D)] into the [said] fluidizing gas flow.

30. [An] The apparatus as set forth in claim 28 [or 29], wherein the [said] fluid supply unit [(3) is arranged to] repeatedly generates [said] single droplets of the coating fluid and [(D),] thereby forms [forming] a stream of such droplets which [(D) that] sequentially impinge upon the [on said] particle [(P)].

31. [An] The apparatus as set forth in claim 24 [any one of claims 24-30], further comprising a control unit [(5)] which monitors [is adapted to monitor] at least one control parameter related to the particle or its environment [of the particle (P) or the particle (P) itself].

32. [An] The apparatus as set forth in claim 31, wherein the control unit [(5) is adapted to] receives the [said] measurement value from the [said] measurement unit and adjusts the [(4) and to effect a change of said at least one] control parameter [based,] at least partly [,] on the basis of the [said] measurement value.

33. [An] The apparatus as set forth in [claim 32 in combination with] claim 26 [or 28], wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein the [wherein said at least one] control parameter comprises [includes] a property of the [said] fluidizing gas flow, [such as a flow rate, a moisture content or a temperature,] and [wherein] the [said] control unit [(5) is operable to effect said change] adjusts the control parameter by controlling the [said] flow unit [(2)].

34. [An] The apparatus as set forth in claim 28 [32 in combination with any one of claims 28-30], wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein [wherein said at least one] the control parameter comprises [includes] a property of the droplet [said droplets, such as a droplet size, a droplet generation rate or a concentration of a droplet constituent], and the [wherein said] control unit [(5) is operable to effect said change] adjusts the control parameter by controlling the [said] fluid supply unit [(3)].

35. [An] The apparatus as set forth in claim 28 [32 in combination with any one of claims 28-30], wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein

the [said at least one] control parameter comprises the [includes a] duration of a droplet generation period; [,] and the [wherein said] control unit [(5) is operable to effect said change] adjusts the control parameter by controlling the [said] fluid supply unit [(3)].

36. [An] The apparatus as set forth in claim 28 [32 in combination with any one of claims 28-30], wherein the control unit receives the measurement value from the measurement unit and adjusts the control parameter at least partly on the basis of the measurement value; and wherein the [said at least one] control parameter comprises the [includes a] duration of a drying period, and the [wherein said] control unit [is operable to effect said change] adjusts the control parameter by controlling the [said] fluid supply unit [(3)].

37. [An] The apparatus as set forth in any one of claims 24-36 and 49-52, wherein the [said] measurement unit [(4) is adapted to] performs the [said] spectrometric measurement by means of near-infrared spectrometry.

38. [An] The apparatus as set forth in any one of claims 24-36 and 49-52 [24-37], wherein the [said] measurement unit [(4) is adapted to] performs the [said] spectrometric measurement by means of a spectrometric method based on Raman scattering.

39. [An] The apparatus as set forth in any one of claims 24-36 and 49-52 [24-38], wherein the [said] measurement unit [(4) is adapted to] performs the [said] spectrometric measurement by means of a spectrometric method based on absorption in the UV, visible, or infrared (IR) wavelength region, or luminescence or [, such as] fluorescence emission.

40. [An] The apparatus as set forth in any one of claims 24-36 and 49-52 [24-39], wherein the [said] measurement unit [(4) is adapted to] performs the [said] spectrometric measurement by means of imaging spectrometry.

41. [An] The apparatus as set forth in any one of claims 24-36 and 49-52 [24-40], wherein the [said] particle [(P)] is a pharmaceutical product [, such as a pellet, a tablet or a capsule].